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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,164	04/01/2004	Esther Regina de Rooij	2183-6412US	1592

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,164	DE ROOIJ ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6,7,14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,6,7,14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed January 29, 2007 is acknowledged and entered. Claims 2-4, 6, 7, 14, 16 and 17 are pending and under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 6, 7, 14, 16 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cassol et al. (Mem. Inst. Oswaldo Cruz, Rio de Janeiro, 1996, 91(3):351-358, "Cassol"). The claims are drawn to a process for preparing at least one sample for a method of detecting and quantifying the amount of a nucleic acid of interest present in the at least one sample, said process comprising:

a) administering at least 100 microliters of the at least one sample to a piece of filter paper capable of absorbing the at least one sample, wherein the absorption results in a at least one spot of the at least one sample of the filter paper,

b) drying the filter paper having the absorbed at least one spot of the at least one sample,

c) excising the at least one spot of the at least one sample from the surrounding filter paper,

d) extracting nucleic acid from the at least one spot of the at least one sample with a nucleic acid isolation solution,

e) detecting nucleic acid of interest, if present, and

f) quantifying the nucleic acid of interest in the at least one sample.

In some embodiments, at least 200 or at least 250 microliters of sample is administered to the filter paper. In other embodiments, at least two samples are administered to the filter paper. Specifically, a known amount of a reference nucleic acid is administered to the filter paper. The nucleic acid of interest is from a virus, specifically, HIV or HTLV, and more specifically, HIV-1.

Cassol's disclosure is related to dried blood spots collected on filter paper, used for diagnosis and genetic characterization of HIV-1 (abstract). A method for the direct automated sequencing of HIV-1 field isolates from dried blood collected on filter paper is described on pages 355-356. The method includes the collection of blood by venipuncture and application of approximately 2 milliliters (2000 microliters) to filter paper via drops. The filter paper is air dried for three hours and placed in individual envelopes for storage/shipment. When the dried blood spots are analyzed, the spots are excised and subjected to PCR analysis. Figure 1 shows the semi-quantitative detection of HIV-1 drug-resistance mutations by automated sequences of dried blood spot specimens using the above-described analysis. Therefore, the teachings of Cassol anticipate Applicant's claimed invention.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

Applicant asserts that Cassol does not disclose a method according to the claimed invention since Cassol does not quantify the amount nucleic acid of interest present in the sample. Applicant points out that Cassol is concerned about what kinds of mutations occur most

frequently, but no information is provided about the amount of nucleic acid of interest in a sample. Applicant concludes that Cassol does not quantify the amount of HIV nucleic acid present in the sample, and thus Cassol's teachings do not meet the limitations of the instant claims.

In response to Applicant's arguments, the Office has considered the particular teachings of Cassol. The Office agrees that Cassol's method is concerned with determining HIV drug-resistance mutations in the HIV genome. The instant claims quantify the amount of nucleic acid of interest, not total nucleic acid content. Cassol's nucleic acid of interest is HIV drug-resistance mutations in the HIV genome. Thus, Cassol meets the limitations of the claims with regard to *nucleic acid of interest.* With regard to Applicant's assertion that Cassol does not quantitatively measure nucleic acid of interest, Figure 1 shows the semi-quantitative detection of HIV-1 drug-resistance mutations by automated sequences of dried blood spot specimens. Therefore, in view of the breadth of the claim language, Cassol anticipates the claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 6, 14, 16 and 17 remain rejected under 35 U.S.C. 103(a) as being obvious over Moye et al. (4th Conference on Retroviruses and Opportunistic Infections, 1997, Abstract, cited in IDS filed 8/9/06, "Moye"). Moye discloses detection and quantification of HIV-1 RNA

from filter paper adsorbed whole blood or plasma by NASBA (nucleic acid sequence-based amplification) isothermal amplification. Moye collected whole blood from HIV-infected subjects. Liquid plasma and whole blood were assayed for HIV-1 RNA by the following method: 100 microliters of whole blood and plasma were spotted onto filter paper and dried. Using lysis buffer, RNA was extracted, amplified and detected. Although Moye does not specific teach the excision of the dried blood spot prior to extracting RNA, one of ordinary skill in the art would have been motivated to excise the spot from the surrounding filter paper if the filter paper were too large to include in the lysis buffer extraction step. The step of cutting the blood spot away from the unused filter paper does not distinguish over the asserted novelty of the instant invention: detecting and quantifying HIV-1 nucleic acid from dried blood spots on filter paper, wherein the blood spot is comprised of 100 microliters of blood. Therefore, Moye's teachings obviate the claimed invention.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

Applicant asserts that Moye does not disclose a method of quantifying nucleic acids of interest. Applicant points to the results of Moye's experiment and concludes that the values provided have such a high degree of uncertainty that any information that can be obtained is nearly meaningless. Applicant argues that since Moye did not succeed in quantifying RNA to any degree of certainty, Moye did not quantify amounts of nucleic acid of interest. Applicant also points to a statement by Moye, "[w]ith further improvement in recovery and precision, this or similar methods could bring HIV-1 RNA quantitation to settings heretofore considered inaccessible."

In response to Applicant's arguments, the Office has considered the teachings of Moye and Applicant's detailed analysis of the data present in the Moye abstract. It is the Office's position that Moye's quantifies the amount of nucleic acid of interest. It is acknowledged that the data obtained is not of the quality that Applicant desires for their method, however, the claim language recites quantifying the amount of nucleic acid, and Moye's method quantifies the amount of nucleic acid. Note that Moye's method did not utterly fail or yield completely meaningless results. The fact that the method can be improved upon does not render the quantification obsolete. Applicant is arguing the degree and quality of quantification, while the claims merely require quantification. Therefore, the rejection of the instant claims is maintained over Moye's disclosure.

Conclusion

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 3/20/07

STACY B. CHEN
PRIMARY EXAMINER